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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,991	11/12/2003	Gabriel Pulido-Cejudo	50499-1A	6527

25277 7590 11/16/2006

NATIONAL RESEARCH COUNCIL OF CANADA
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CANADA

EXAMINER

YU, MISOOK

ART UNIT PAPER NUMBER

1642

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/705,991

Applicant(s)

PULIDO-CEJUDO, GABRIEL

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/538,831.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/30/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Exhibit 1</u> . |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group 1 claims 1-4 in the reply filed on 8/14/2006 is acknowledged. The traversal is on the ground(s) that method steps in the two restricted groups comprise determining the levels of es-LAPase in a sample. This is not found persuasive because the elected group is to detect breast cancer, and group II is to detect metastatic cancer. Searching a marker for cancer and metastasis involve divergent searches, especially in non-patent literature, and put a serious burden on the examiner. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-8 are pending. Claims 5-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Claims 1-4 are examined on merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "es-LAPase" but it is not clear what the meets and bounds are. Searching of the term in PubMed does not generate any reference that uses the term, which indicates that the term is not accepted in the art. See Exhibit 1.

For the purpose of this Office action, the term is interpreted as serum leucine aminopeptidase. However, this treatment does not relieve applicant the burden of responding to this rejection.

Claim Rejections - 35 USC § 102

Claims 1- 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Gupta et al., IDS, Indian J Pathol Microbiol, 1989 Oct;32(4):301-5.

Claims 1 and 3 are drawn to a method of breast cancer diagnosis by detecting es-LAPase

Gupta et al., teach a serum leucine aminopeptidase is elevated in breast cancer patients (see the abstract). Since the specification at page 20, Examples 5 uses LAPase in plasma of breast cancer patient, it is assumed that the total leucine aminopeptidase including estrogen-stimulated LAPase and other LAPase are included in the claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta et al (cited above) in view of Deng et al (IDS, 1996, Hepatology, vol. 23, pages 445-453).

Claims 1 and 3 are drawn to a method of breast cancer diagnosis by detecting es-LAPase by immunoassay.

Gupta et al., teach serum aminopeptidase is elevated in breast cancer patient but does not teach immunoassay measurement of the level of the enzyme.

However, Deng et al., teach AD-1 hybridoma producing monoclonal AD-1 antibody capable of binding membrane associated human leucine aminopeptidase. See abstract, Patients and Methods at page 446, Fig. 3, Fig. 5 and Fig. 8). The monoclonal AD-1 antibody appears to detect multiple forms of LAPase either due to isoforms or different forms of multicomplex with other membrane components (see Figure 3 C of the reference at page 449). Therefore, it would have been obvious to one of ordinary skill in the art to use the immunoassay method to detect LAPase with a reasonable expectation of success since Deng et al., teach the necessary reagent for the method.

Allowable Subject Matter

Claim 4 is free of art. Applicant's biological material deposit statement is noted in the Amendment (Paper No. 12) in the parent case (09/538,831).

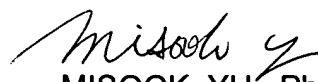
Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MISOOK YU, Ph.D.
Primary Examiner
Art Unit 1642



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